UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,295	07/25/2006	Adam Dan	06423/LH	4922

1933 7590 10/07/2009

FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
220 Fifth Avenue
16TH Floor
NEW YORK, NY 10001-7708

EXAMINER	
BRUTUS, JOEL F	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
10/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,295	DAN, ADAM	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-17 and 20-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 1, it is not clear what it means by improve likelihood. The word "likelihood" is not a positive recitation which renders the claim indefinite.

Regarding claims 2-17 and 20-37, they are rejected because they depend on claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 8-11, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Grandia et al (US Pat: 5,827,204).

Regarding claims 1-3, 8-11, 15, and 17, Grandia et al teaches a medical noninvasive operations using focused modulated high power ultrasonic includes a transmitter for exiting a multifrequency ultrasound wave for causing vaporous cavitation

bubbles in a small focal zone of a medical target region that anticipates the claimed invention. Grandia et al further teaches the multifrequency wave includes an underlying low frequency signal for enabling optimal growth of micro bubbles and at least one high frequency signal for enabling a narrow zone of focus of the ultrasound [see abstract]. The system is provided with a cavitation monitor to sense a level of cavitation as well as providing feedback to the transmitter [see abstract]. In addition, an imaging system is provided for enabling viewing of the medical target area during the therapy [see abstract]. The invention is used to dissolve a medical target such as blood clot in a vessel using high energy vaporous cavitation confined to a small focal zone [see column 4 lines 1-3]; at least one ultrasonic transmitter which provide means for inducing a modulated multifrequency ultrasound wave [see column 4 lines 12-15]; a low frequency signal that is less than 100 kHz, preferably 25 KHz [see fig 2A and column 4 lines 20-25]; modulated wave has frequency and amplitude parameters chosen for both maximizing the cavitation effect of the wave when transmitted into the medical target region and establishing the narrow focal zone when cavitation will occur [see column 4 lines 32-35]; method for non invasive procedures using focused modulated high powered ultrasound for dissolving thrombi, promoting blood clotting and destroying malignant and benign tumors in living tissue; ultrasonic waves offer a means for delivering high powered mechanical energy for disintegration of medical targets by heating the target with focused ultrasound or by ablation of the target with ultrasound shock waves [see column 1 lines 10-20]; using in conjunction with medicinal fluids, for example thrombolytic agents [see column 1 lines 27-35]. Carefully chosen parameters

for controlling and optimizing the effect of cavitation in a region [see column 2 lines 42-44]; the dimension of focal zone may be controlled by selecting a curvature of the focused modulated high power transmitter and the high frequency value [see column 6 lines 33-35].

Grandia et al teaches low frequency ultrasonic waves can be transmitted at high powers sufficient to perform tasks by heating or dissolving unwanted tissues [see column 4 lines 40-44]; ultrasonic energy is useful for dissolving tissues and heating tissues due to formation and violent collapse of cavitation bubbles [see column 4 lines 47-50]; Vaporous cavitation implosions produce a violent effect which can be useful for medical purposes only if cavitation takes place is spatially controlled as to not damage adjacent tissue [see column 5 lines 1-5]; the size of cavitation decreases with an increase of frequency, cavitation bubbles grow larger at lower frequencies due to the longer period between the rarefaction and the compression parts of the wave [see fig 2a-c and column 5 lines 18-25]; a longer wavelength allow bubbles to grow larger before they collapse [see column 5 lines 23-25]; the transmitter may comprise a combination of transducers or single focused transducer which is driven to produce two or more frequencies such as high and low frequency signals in continuous or tone burst mode; the low and high frequency signals can be excited by the single focused transducer as radial and harmonic components respectively [see column 5 lines 40-50] and the use of a transducer array [see column 7 lines 30-31].

Grandia et al teach a transmitter 18 that may comprise a combination of transducers, or a single focused transducer 56 which is driven to produce

simultaneously two or more frequencies in, such as the high frequency signal 34 and low frequency signals 32, in either continuous or tone burst mode [see column 7 lines 40-50]. Grandia et al also teach a low power ultrasonic field is transmitted through the medical target area in order to produce a visual image of the area being treated. This may be accomplished, for example, by use of an array transducer ultrasonic imaging system, such as Model UT-3D (QMI, Costa Mesa, Calif.) or by use of a high frequency ultrasonic transducer 66b, forming a part of an imaging axicon transmitter and receiver, which produces a pencil shaped, low power high frequency ultrasound field in the medical target region [see column 7 lines 26-34].

Grandia et al teaches the multifrequency signal may be transmitted in burst to enhance operation efficiency and to control the effect of temperature rise and cavitation implosion, destroying blood clots, short burst and long delay cause formation of cavitation with minimum heating thus enhancing the blood clot disintegration mechanism [see column 5 lines 58-65]. The creation of blood clot may be used for destroying cancerous growths; the heating effect of cavitation can be used to create blood clots in order to prevent a blood supply from nourishing and supporting the abnormal growth [see column 6 lines 1-12]; the present invention can be used for coagulating blood in order to stop uncontrolled bleeding, disintegration of tissue, blood clot creation [see column 6 lines 15-20]; means for positioning the focal zone, actuator pushes the transmitter and imaging probes to desired position [see column 6 lines 35-38]; positioning the focal zone into a medical target region surrounding or adjacent to, an abnormal growth, thrombosis [see column 6 lines 50-55]; monitoring of cavitation is

performed during positioning of the focal zone in the target region [see column 7 lines 20-24]; digital signal processor, wide band amplifier, video display mode, monitor, personal computer with high and low frequencies control [see fig 4 and column 7 lines 5-65]; Fig 2a-c shows waveforms with high negative peaks and small position peaks, also high positive peaks and small negative peaks, cavitation threshold, cavitation collapse threshold, high frequency signal, low frequency signal, rarefaction and compression parts [see fig 2a-c].

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 4-6, 12-13, and 16, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandia et al (US Pat: 5,827,204) in view of Acker et al (US Pat: 6,508,774) and further in view of Cathignol et al (US Pat: 5,219,401).

Regarding claims 4-6, 12-13, and 16, 18-19, Grandia et al teaches all other limitations as se forth above.

Grandia et al doesn't teach three transducers, adjusting waveforms to include more negative peaks, more positive peaks; coupling gel.

However, Acker et al teaches in fig 1 at least transducers, a feedback control to indicate cavitation when amplitude exceeds a threshold; moving focal location relative to

body in response to feedback signal, altering therapeutic ultrasonic waves by redirecting them to a different focal location [see column 4 lines 12-30]. Positioning an array of transducers adjacent the body of subject, within the body or on the skin; the transducers can be coupled to the body using a fluid filled bag and sound transmissive gel [see column 4 lines 42-54]. Drive signal generator to produce one or more series of digital values representing a waveform [see column 6 lines 27-29]; a control computer linked to phase shifts unit, evaluation unit [see column 6 lines 40-50]; a control unit actuates generator to generate a drive signal at a selected therapeutic drive signal frequency band [see column 8 lines 1-4]; control unit that can reduce the amplitude of the drive signals or superimpose an additional components such as higher frequency component intended to suppress cavitation [see column 10 lines 45-48]. Detection band may be selected to encompass a harmonic frequency [see column 11 lines 10-12]; each transducer actuated individually to apply waves [see column 12 lines 21-23]. Grandia et al doesn't teach micro bubbles in the range of up to 100 or more microns.

However, Cathignol et al teaches an apparatus for generating gas bubbles to be destroyed within the cells, implosion means to implode bubbles, high power acoustic wave generating means (at least three generators denoted 24-26) [see column 6 lines 54-55], focusing means for in target focusing [see column 5 lines 28-65]. Means for tracking and locating cells to be destroyed, central control device [see column 6 lines 38-55]; mechanical shock wave generators [see column 6 lines 5-6]. Cathignol et al discusses the size of bubbles and diameter in the range of 0.1 and about 300 microns

[see column 7 lines 30-40]; destroying the cells due to cavitation Phenomena [see column 7 lines 42-14].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by using the at least three transducers of Acker et al; for the purpose of treating malignant tissues with efficiency; the use of a coupling gel to provide a low reflectivity interface; thereby enhancing the transmissive properties of the transducers. Harmonic imaging provides the opportunity for determining the particular size distribution of micro bubbles.

Telangiectasias are small dilated blood vessels near the surface of the skin or mucous membrane and varicose vein are twisted veins in the leg. The above combination provides treatment or therapy intravenously, treating blood clots etc... However, an artisan would occluse varicose vein and telangiectasia; to improve the patient's health and to enhance cosmetic appearance and relive pain that occurs with varicose veins.

7. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandia et al (US Pat: 5,827,204) in view of Cain et al (US Pat: 6,413,216).

Regarding claims 20-21, Grandia et al teaches all other limitations as set forth above.

Grandia et al doesn't teach gene therapy.

However, Cain et al teaches a therapeutic ultrasound system and a diagnostic system to produce cavitation and include one or more transducers; each transducer can

be adjusted to form a highly focused ultrasound beam which can be formed at a specific location within treatment volume; the beam can be adjusted to compensate for acoustic aberrations and can be adjusted to follow movement of treatment volume [see column 4 lines 44-60]. Drug cavitation can be delivered and activated within treatment volume; the drugs reagents can be encapsulated within a micro bubbles, blood clotting drug can be delivered [see column 7 lines 55-65].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Grandia et al and Cain et al references; for the purpose of providing treatment with much faster results; and treating coronary arteries in order to improve treatment of cardiac patients.

8. Claims 22-26, 28-32, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandia et al (US Pat: 5,827,204) in view of Acker et al (US Pat: 6,508,774) and further in view of Cathignol et al (US Pat: 5,219,401) as applied to claim 1 above, and further in view of Egami et al (US Pat: 4,618,831).

Regarding claims 22-26, 28-32, and 36-37, the above combination teaches all other limitations. Grandia et al teaches a personal computer that can be used as a workstation and control unit would provide the same as a control box, one wide range amplifier [see column 7 lines 52-65].

The above combination doesn't teach three wide band amplifiers.

However, Egami et al teaches an apparatus that has a plurality of amplifiers that operates over a wide range [see column 3 lines 1-5].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Grandia et al and Egami et al references by using three wide ban amplifiers; for the purpose of manipulating the amplitudes of the signals and to increase the system capability.

9. Claims 7, 14, 27, 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandia et al (US Pat: 5,827,204) in view of Acker et al (US Pat: 6,508,774) and further in view of Cathignol et al (US Pat: 5,219,401) as applied to claim 1 above, and further in view of Egami et al (US Pat: 4,618,831) and further in view of Laugharn, Jr et al (Pub. No.: US 2002/0009015).

Regarding claims 7, 14, 27, 33-35, all other limitations are taught as set forth above.

The above combination doesn't teach annular array; -3dB, temperature measurement system and one or more thermocouple.

However, Laugharn Jr et al teaches annular array in conjunction with focusing electronics to create focused beam [see 0056]; a focal zone defined as having an acoustic intensity within about 6 dB of the peak acoustic intensity and the focal zone that has a diameter of approximately 2 mm and an axial length of about 6 mm [see 0060]. Temperature can be monitored by probe such as thermocouple and be monitored by the same computer that controls acoustic waveform [see 0119]; sensor to check temperature [see 0120-0125].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Grandia et al and Laugham, Jr et al references; for the purpose of reducing acoustic side lobes near the focal point; heating the target/tissue to a temperature sufficient to create a desired therapeutic effect; to destroy unwanted tissues in the body without destroying adjacent normal tissues. One with ordinary skill would be motivated to use -3 DB because of the ability to conveniently represent very large or small numbers, a logarithmic scaling that roughly corresponds to the human perception, -3 DB meaning the reference value is greater than the actual; thereby it would generate more negative peaks.

Response to Arguments

10. Applicant's arguments filed 5/18/2009 have been fully considered but they are not persuasive. The rejection to the abstract is moot due to the amendment.

Applicant argues that Grandia et al don't teach selecting a range of parameters of the ultrasound waves to improve cavitation.

The Examiner disagrees because Grandia et al teach carefully chosen parameters for controlling and optimizing the effect of cavitation in a region [see column 2 lines 42- 44]; the dimension of focal zone may be controlled by selecting a curvature of the focused modulated high power transmitter and the high frequency value [see column 6 lines 33-35].

Applicant also argues that Grandia et al don't teach simultaneously directing ultrasound waves from the transducers.

However, Examiner disagrees because Grandia et al teach a transmitter 18 that may comprise a combination of transducers, or a single focused transducer 56 which is driven to produce simultaneously two or more frequencies in, such as the high frequency signal 34 and low frequency signals 32, in either continuous or tone burst mode [see column 7 lines 40-50]. Grandia et al also teach a low power ultrasonic field is transmitted through the medical target area in order to produce a visual image of the area being treated. This may be accomplished, for example, by use of an array transducer ultrasonic imaging system, such as Model UT-3D (QMI, Costa Mesa, Calif.) or by use of a high frequency ultrasonic transducer 66b, forming a part of an imaging axicon transmitter and receiver, which produces a pencil shaped, low power high frequency ultrasound field in the medical target region [see column 7 lines 26-34].

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768